REMARKS

The above-noted amendments to claim 1 and addition of new claims 17-23 are respectfully submitted in response to the official action dated July 8, 2005. In addition, the Specification and claim 13 have been amended in order to correct typographical errors therein. No new matter is included in any of these amendments.

In view of the nature of these amendments, the overall nature of the present invention, and the distinctions between the present claims and the prior art, it is respectfully submitted that all of the claims in this application are now in condition for allowance, and such action is therefore respectfully solicited.

The present invention includes a number of aspects which are quite distinct from and superior to the prior art, including the cited references. Most particularly, in accordance with the present invention, great flexibility is now possible when using applicants' claimed method in order to ease a patient's pain and anxiety in connection with both atrial and ventricular defibrillation. Thus, not only is it possible for specified medical gases to be effectively utilized by a patient in connection with activation of an atrial or ventricular defibrillation device, while at the same time remotely communicating information directly from the atrial defibrillation device to third parties, such as doctors, nurses, and other medical professionals, to assist the patient in the application of the medical gas and/or the patient's activation of the defibrillation device itself, and/or in remotely activating the defibrillation device itself or remotely releasing the medical gas administration device for use, but in other aspects of the present invention the heretofore unknown use of N_2O/O_2 combinations for this purpose can now be effectuated. In addition, the present invention provides a

method by which such medical gases can be immediately inhaled subsequent to ventricular defibrillation, and which can also be done in connection with remote communication of information to third-party professionals. In each of these aspects, the present invention provides not only differences but significant medical differences as compared to the prior art hereagainst.

In that regard, claims 1-16 have been rejected as being unpatentable on the basis of obviousness-type double patenting over claim 6 of Ujhelyi *et al.* in view of Brooks. The Examiner contends that the claims would be obvious because they resulted from the use of the device of claim 6 of Ujhelyi *et al.* In addition, it is contended that because claim 6 states "inhalation," it would be obvious the drug would be a gas which would allegedly inherently produce one of the claimed effects. In addition, reference is made to Brooks as an inhalant to reduce stress producing analgesia. It is thus said to be obvious to use a gas producing an analgesia effect, including the gases taught by Brooks.

As for claims 2 and 10, Brooks is said to teach the specific gases of claim 2, and it is said to be obvious that the pain control would need to be maintained prior to, during and after defibrillation for patient comfort.

Regarding claims 3, 4, 8, 11, 12, and 16, it is said to be obvious to have a specific gas mixture, as different users require different mixtures to provide the ideal analgesia effect. Regarding claims 5 and 13, the limitations thereof are said to be found in claim 6, lines 19-24 regarding the gas being delivered immediately prior to activating the atrial defibrillation implantable cardioverter defibrillator.

Regarding claims 6, 7, 14, and 15, it is said to be obvious to arrive at the claimed time range for delivery, as

different users may require longer or shorter time range to provide the analgesia effect. This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

It is initially noted that the cited Ujhelyi *et al.* reference is assigned on its face to Medtronic, Inc. The present application, on the other hand, is assigned to AGA AB of Sweden. Therefore, even though one of the inventors of the Ujhelyi *et al.* patent is one of the co-inventors in the present application, this does not provide a basis for the institution of a double-patenting rejection. It is thus clear that the sole rejection in this case based on double patenting is inappropriate, and should be withdrawn.

In any event, applicants have treated this rejection as a simple obviousness rejection based on the earlier-filed Ujhelyi *et al.* patent itself.

Turning to the Ujhelyi *et al.* patent, while it is generally directed to the control of pain associated with electrical therapy, it is strictly limited to telemetric communications between an external drug delivery arrangement and an implanted device (ICD) strictly for use by a patient to alert for an arrhythmia condition. Thus, upon detection of fibrillation by the ICD, the ICD communicates to an external drug delivery arrangement, providing an alert of the fibrillation condition to the patient. When the drug is then administered by the patient, the drug delivery arrangement communicates to the ICD that this has occurred so that defibrillation can continue. The disclosure of Ujhelyi *et al.* is thus specifically limited to two-way communications between the implanted ICD and the non-implanted drug delivery device. Indeed, the disclosure of Ujhelyi *et al.* does not add very much beyond this disclosure. For example, although it does refer to the patient "inhaling" a drug from a reservoir, there is no

specific reference even to the general use of gases, much less the specific gases to which a number of the present claims are directed. This is not too surprising, however, since the use of gases such as N_2O/O_2 has never been considered for the purposes of the present invention.

In any event, the primary purpose of the Ujhelyi *et al.* invention, and the two-way communications established thereby, is solely to give the patient sufficient time upon being alerted by the ICD to absorb the drug before applying electrical therapy.

Turning to the present claims, however, it is noted that claim 1 is specifically directed to a method which is far more flexible and useful than that of Ujhelyi *et al.*, and which specifically requires remotely communicating information relating to activation of the atrial defibrillation device so that third parties such as medical professionals including doctors, nurses, EMTs and the like, can consider this information, and then assist the patient in inhaling an effective amount of the medical gas from a medical gas administration device, and/or remotely activating the atrial defibrillation device or remotely releasing the medical gas administration device. This is an extremely important element of the present invention which is nowhere suggested by Ujhelyi *et al.*

In addition, the specific limitation of many of these claims, including newly added claim 17, to the application of N_2O/O_2 gas mixtures, and the specific time limits for administration of less than four minutes prior to atrial defibrillation, constitute significant additional differences over the art. There is no prior art which thus discusses the use of N_2O/O_2 mixtures for such short periods of time for purposes of pain management, sedation, or anterograde amnesia, for any medical condition, including atrial defibrillation. In

fact, studies and considerable effort as illustrated within Examples 1, 2, and 9 of the specification were required in order to develop this knowledge, and provide a key basis for the present invention itself.

As for the attempt to overcome the clear deficiencies of Ujhelyi *et al.* with Brooks, this is deemed to be less than helpful. The Brooks patent itself makes no mention of atrial defibrillation or the like. Indeed, this patent is generally directed to achieving reduced perceived stress in humans by a specific inhalant composition comprising nitrogen, sufficient oxygen to reduce asphyxia, an inert gas, and an anesthetic agent sufficient to produce anesthesia. Furthermore, the overall thrust of the Brooks patent is as an aid to stop smoking, or following a deep sea dive to alleviate the effects of high pressure environments, during childbirth, and to reduce stress of an animal. It is also noted that, contrary to even the suggestion of use in connection with atrial defibrillation (or regarding use within close proximity to a defibrillating shock on a time basis), these instances are not time sensitive, and there is no need for the timing of communication with respect to these treatments. More significantly, however, N_2O is the only active analgesic gas in the specific admixture cited by Brooks, which includes a number of other gases which are not helpful in connection with the present invention. Furthermore, Brooks does not disclose the amounts of N_2O which are claimed for example in claims 3, 4, 11, and 12. To the contrary, while disclosing a broader range, the preferred range in Brooks is 1% to 10% N_2O, an amount which would hardly even effect analgesia, particularly in the face of a pain generating event, much less the other important effects of the present invention. This reference certainly does not teach or suggest the one-time administration for up to four minutes prior to defibrillation of N_2O in accordance with claims such as claim 17. Furthermore, there

would be no motivation whatsoever to combine Brooks with Ujhelyi *et al.* to achieve anything like the results of the present invention.

We would next note that the Examiner does not make specific reference to claim 9, and with good reason. Returning to Ujhelyi *et al.*, this patent is clearly directed to atrial defibrillation. Indeed, since it is well known in the art, and is specifically spelled out in claim 9, that ventricular defibrillation requires immediate electrical stimulation, and that there would be no time to wait to apply any medical gas or other drug prior to electrical defibrillation, this would certainly not even be possible with the method disclosed in Ujhelyi *et al.* The overall discussion in Ujhelyi thus relates solely to signaling of the fibrillation, and effecting electrical defibrillation after the patient has applied the drug. Offhand reference to various heart conditions, including ventricular fibrillation, in this disclosure does not alter the overall nature and substance of this disclosure and the fact that it is clearly directed to atrial defibrillation and the ability to respond thereto. It is therefore abundantly clear that claim 9 is nowhere suggested by the prior art, including Ujhelyi *et al.*, and that this claim and the claims dependent thereon are clearly patentable thereover.

It is therefore respectfully submitted that all of the claims now contained in this application clearly possess the requisite novelty, utility and unobviousness to warrant their immediate allowance, which action is respectfully solicited. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone applicant's attorney at (908)

654-5000 in order to overcome any additional objections which she might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: October 11, 2005

Respectfully submitted,

By_____

Arnold H. Krumholz
Registration No.: 25,428
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicant

596052_1.DOC